

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAR 10 1987

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCE

MEMORANDUM

SUBJECT: Amended TAS Analysis of Avermectin on Citrus.  
PP#7G3468/FAP#7H5518.

TO: George LaRocca (15)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)

FROM: D. Stephen Saunders, Ph.D.  
Acting Program Manager, TAS  
RCB/HED (TS-769C)

DS 3/9/87

THRU: Charles L. Trichilo, Ph.D.  
Chief, Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

Action Requested

Provide a revised TAS analysis of the proposed use of Avermectin on citrus to reflect the higher tolerance in meat of 0.01 ppm, per the memo Cheng to LaRocca, 2-11-87. This is in compliance with the policy recently established in HED that the TAS will be used for tolerance requests on new chemicals.

Recommendations/Discussion

A. Analysis of Chronic Dietary Exposure: The residues used in this analysis were those proposed by registrant for citrus (0.005 ppm) and milk (0.001 ppm). A tolerance of 0.01 ppm has been determined by RCB to be appropriate for meat; this value was used rather than the value of 0.005 ppm proposed by the Registrant. The Reference Dose (RfD, ADI, RDV) used in this analysis was 0.0012 mg/kg/day, which was derived from a NOEL of 0.12 mg/kg/day in a rat reproduction study, with a safety factor of 100. This value has not been verified by the appropriate Agency committees. A listing of information on residues and the proposed ADI is appended.

The proposed use would result in a TMRC for the U.S. population average of 0.000038 mg/kg/day, which would correspond of 3.2% of the ADI proposed by the Toxicology Branch reviewer. The most highly exposed subgroups would be non-nursing infants (0.000105 mg/kg/day, 8.8% of the ADI) and children 1-6 years of age (0.000092 mg/kg/day, 7.7% of the ADI).

*Note to PM - The safety factor to be used for calculating the PADI has been changed from 100 (as used in this memo) to 1000. Therefore, all percentages of the PADI used up will be increased by a factor of 10. D.S. 2/10/87*

B. Analysis of Acute Dietary Exposure: This analysis serves as a screen to determine if an acceptable margin of safety (MOS) exists for an acute effect. In the present case, a NOEL of 0.06 mg/kg/day for developmental effects was identified by Toxicology Branch.

The TAS Menu Screen analysis determined that the highest predicted exposure of females 13 years of age and older would be 0.00005 mg/kg/day. Using the formula:

$$\text{MOS} = \frac{\text{NOEL}}{\text{Exposure}} = \frac{0.06}{0.00005}$$

it was determined that an MOS of at least 1200 exists for the proposed uses as they relate to this developmental endpoint.

DSS:RCB/HED:3-09-87:FILE 063AB.TOL

ATTACHMENT

cc: Reading File  
Avermectin SF  
TAS File  
circ.

PMSD  
W. Dykstra (TOX)  
S. Rathman (TOX)